REMARKS

Applicants note that the Office Action was again sent by mail to an incorrect law firm, although Applicants had identified this clerical error in their Amendment filed on July 12, 2002. Applicants again request that the Examiner forward all future correspondence to their Attorney of record, Richard H. Zaitlen, Esq., at the address indicated below.

Applicants have studied the Office Action of October 22, 2002. Claims 12-18, 20-23, 43-58 and 60-70 are pending in the present application. Claims 12-18 and 20-23 stand withdrawn from consideration pursuant to 37 CFR 1.142(b); claims 43-58 and 60-62 have been allowed; and claims 63-70 stand rejected. Reconsideration and allowance of the claims in view of the ensuing remarks are respectfully requested.

The Applicants thank the Examiner for allowing claims 43-58 and 60-62.

The Examiner rejected claims 63-70 under 35 U.S.C. § 112, first paragraph, stating that the specification "does not reasonably provide enablement for a nucleotide sequence consisting of a sequence which is 60% identical to SEQ ID NO:2 and SEQ ID NO:3." This rejection is respectfully traversed.

The Examiner argues that claim 63 is overly broad in its recitation of "60% identical" because a "myriad of polynucleotide species [are] encompassed by the claim," and the specification does not disclose how one can be sure that any of these sequences will "retain the characteristics of TfR." In describing the claims this way, the Examiner leaves out an important limitation: a nucleotide sequence does not fall within the scope of the claims unless it "encodes a polypeptide that binds transferrin when the nucleotide is transfected into a cell that lacks transferrin receptors and the cell is incubated with 5 µg/ml of transferrin in nutrient media for 30 min on ice." The range of nucleotide sequences that the claims encompass is therefore not as broad as the Examiner states; not only must a nucleotide sequence have "at least 60% sequence homology" with respect to the nucleotide sequences recited in the specification, but it must also pass a specific functional test.

Applicants respectfully submit that the standard for enablement is not as severe as the Examiner has put it. As long as an applicant "discloses at least one method for

making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." MPEP 2164.01(b) (emphasis added). Claims may be enabled even if those skilled in the art reasonably disagree as to whether they are enabled or not. Bio-Technology General Corp. V. Genentech, Inc., case no. 00-1223, -1267 (Fed. Cir., September 27, 2001). But here, Applicants have done precisely as the MPEP has required: they have disclosed, over 12 full pages of the specification, examples that describe at least a dozen cell lines that may be used to derive the nucleic acid sequences of the invention, a procedure to clone cDNA and genomic DNA isolated from these cell lines, a chromosomal mapping technique to identify genes carrying the nucleic acid sequences of the invention, and Northern blot, reverse-transcriptase chain reaction, transfection, flow cytometric analysis, and other techniques to evaluate and isolate the these sequences. See pages 21-33 of the application. This procedure enables any one of ordinary skill in the art (and Applicants repeat here their observation that the level of skill in the art is very high) to make and use the nucleic acids of the invention commensurate in scope with the claims.

This is not to say that one seeking to identify nucleic acids other than those disclosed in the specification will not have to conduct experiments to do so. But experimentation is permissible. Even "a considerable amount of experimentation is permissible, if it is merely routine." In re Wands, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). In United States v. Telectronics, Inc., 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988), for example, competitors had to experiment for 6 to 12 months, call upon four different specialtists (an electrical engineer, a surgeon, a biomechanic, and a biologist), and spend $50,000 to determine how to practice the invention at issue; yet even this amount of experimentation was not undue, because the steps required to carry it out were routine. The same principal applies in the present application. Those of ordinary skill in the art will have to execute no more than routine steps – all of which the specification describes in many pages of detail – to identify and use nucleic acid sequences which have "at least 60% sequence homology" to the sequences identified in the specification. Applicants therefore respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

For the foregoing reasons, Applicants believe that the application is condition for allowance, and respectfully request early, favorable action on the merits. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance should the Examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

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Date: November 6, 2002

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